Transcom	TECHNICAL EVALUATION DOCUMENTATION	# Document: HC-1/HC-1 CLASSIC HYDROKIT

SECTION 5 – 510(k) SUMMARY

DATE OF SUBMISSION: 2014-02-13

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DEVICE TRADE NAME: TRANSCOM COLON HYDROTHERAPY
MODELS HC-1 and HC-1 CLASSIC
And HYDROKIT

COMMON NAME: COLONIC IRRIGATION SYSTEM
CLASSIFICATION NAME: COLONIC IRRIGATION SYSTEM (21 CFR 876.5220)

PREDICATE DEVICE: TRANSCOM COLON HYDROTHERAPY MODEL HC-2000 (K970482)

DEVICE DESCRIPTION:

The HC-1 and HC-1 Classic proposed device is a device for colon cleaning. It introduces water at a comfortable temperature into the large intestine. It automatically fills and empties water into and out of the colon thus cleansing it of its contents when medically indicated such as before radiological or endoscopic examination. It is hygienic, painless and odorless. The device is equipped with an automatic pressure safety system; integrated disinfectant container, flow regulator and a 3-way manifold. It is supplied with disposable probe/hose assemblies for single-use during colonic hydrotherapy.

The HYDROKIT is a colonic irrigation system intended to instill water into the colon through a nozzle inserted into the rectum to evacuate the contents of the lower colon.

SUMMARY OF COMPARISON WITH PREDICATE DEVICE:

In the establishment of substantial equivalence, The HC-1 model is compared with the previously cleared Transcom HC-2000 model for colonic irrigation (K970482).

The following table summarizes the similarities of the principal technological characteristics and features of both predicate and new devices.

#	Characteristic / Feature	PROPOSED DEVICE HC-1 / HC-1 Classic	PREDICATE DEVICE HC-2000 (K970482)
1.	Chassis material	Stainless steel casing	Steel casing with zinc additive for anti-corrosion

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2.	Dimensions	530 x 600 x 1020 (HC-1) / 610 x 230 x 600 mm (HC-1 Classic)	970 x 600 x 120 mm
3.	Installation type	Mobile (HC-1) / Fixed (HC-1 Classic)	Fixed
4.	Pre-installation requirements	Cold and hot water	Cold and hot water
		Pressure regulator 2 bar	Pressure regulator 2 bar
		Syphon as low as possible	Syphon as low as possible
		Electrical water heater 60 liters	Electrical water heater 60 liters
		Waste output tube	Waste output tube
5.	Filters	2 x 5μm filters	2 x 5μm filters
6.	U.V. light	YES	YES
7.	Water heating	Needs electric heater	Needs electric heater
8.	Features / Functions		
	- process display	NO	NO
	- flow meter	0 – 100 liter/hour	0 – 100 liter / hour
	- manometer	250 mbar	200 mbar
	- session time	NO	Automatic, programmable
	- fluorescent light	Static, protected	Static, protected
	- irrigation liter counter	NO	YES
	- irrigation time counter	NO	YES
	- front panel control	NO	YES
	- remote control	NO	YES
	- digital thermostat	YES, 2 alarms	YES, 2 alarms
	- sample collection	NO	YES
	- visor	Protected	Protected
	- syphon	External	External
9.	Cleaning system		
	- water	Manual	Automatic
	- disinfectant	Manual	Automatic
10.	Presostat setting	Cuts out at 150 mbar	Cuts out at 100 mbar

From the above table, it can be established that the new device and the predicate device are very similar. In fact, the proposed device is a simpler version of the HC-2000 model.

About the Hydrokits:
The Hydrokits have the same technological characteristics as, and are substantially equivalent to the SPO1 and SP02 disposable speculums (K000388), manufactured by Clearwater Colon Hydrotherapy Inc. The only difference is the insertion stopper present on one of the models of Hydrokits.

The material used to manufacture the speculum & obturator is SASOL HNR100 polypropylene copolymer which meets FDA requirements 21CFR 177.1520. The finished Hydrokit Speculum was tested for biocompatibility by BIOLAB Laboratory in Spain

Kit components packaged with the Hydrokit disposable speculum (water line, waste hose, & surgical lubricant) are substantially equivalent to those included with the SP01 and SP02 disposable speculums, manufactured by Clearwater Colon Hydrotherapy Inc.

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INTENDED USE:
The device is intended for use to cleanse the colon when medically indicated, such as before radiological or endoscopic examination

SUMMARY DISCUSSION OF NON-CLINICAL DATA:

HC-1 and HC-1 Classic:
The proposed device has been subject to bench testing to determine conformance to performance specifications and requirements taking account of its intended use as a colon irrigation system.

Functional laboratory testing performed in foreseeable operating conditions showed correct operation of the device as per its intended use, specifically including:

- Correct electrical safety
- Electromagnetic compatibility
- Delivery of colon hydrotherapy in accordance with device performance specifications

No animal or clinical testing was performed on the proposed device

Hydrokits:

The proposed device has been subject to bench testing to determine conformance to performance specifications and requirements taking account of its intended use as a colon irrigation system.

The bench tests performed are biocompatibility testings and mechanical testings:

- **Biocompatibility**
  - Cytotoxicity
  - Sensitization
  - Irritation or intracutaneous toxicity
- **Mechanical**
  - Tensile
  - Compresion

SUMMARY DISCUSSION OF CLINICAL DATA:
No clinical studies are submitted to support this premarket notification.

CONCLUSIONS:
HC-1 and HC-1 Classic:
We believe the intended use, the indications for use, the functionality and the operation of both HC-1 and HC-1 Classic variants are essentially the same as the predicate HC-2000 device. Hence, substantial equivalence of the TRANSCOM COLON HYDROTHERAPY MODEL HC-1 / HC-1 CLASSIC with the legally marketed device may be established.

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Hydrokits:

We believe the intended use, the indications for use, the functionality and the operation of Hydrokit is essentially the same as the predicate Clearwater Colon Hydrotherapy, Inc. Disposable Speculum. Hence, substantial equivalence of the Hydrokit with the legally marketed device may be established.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 17, 2014

Transcendencias Comerciales SL TRANSCOM
Ramon Echevarria
General Manager
C/ZUBIBERRI 31 - PLANTA BAJA LOCAL 1
San Sebastian, Guipuzcoa 20018
Spain

Re: K131852
Trade/Device Name: TRANSCOM COLON HYDROTHERAPY
MODELS HC-1 and HC-1 Classic
And HYDROKITS
Regulation Number: 21 CFR§ 876.5220
Regulation Name: Colonic irrigation system
Regulatory Class: II
Product Code: KPL
Dated: February 13, 2014
Received: February 20, 2014

Dear Ramon Echevarria,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.
You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

PREMARKET NOTIFICATION
INDICATIONS FOR USE STATEMENT
(as required by ODE for all 510(k) received after Jan. 1, 1996)

510(k) Number: K131852

Device Name: TRANSCOM COLON HYDROTHERAPY
MODELS HC-1 and HC-1 Classic
And HYDROKITS

Indications for Use:

The use of this device is restricted to colon cleansing when medically indicated, such as before radiological or endoscopic examination.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Herbert P. Lerner -S
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Prescription Use ✓ (21 CFR 801 Subpart D) OR Over-The-Counter Use ___ (21 CFR 801 Subpart C)